# LANL completes CRADA with Biomagnetics, Inc.

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Los Alamos, New Mexico, Sept. 23, 2011 — Los Alamos National Laboratory successfully completed a Cooperative Research and Development Agreement (CRADA) with Biomagnetics Diagnostics, Inc., in June 2011. The CRADA followed the licensing to Biomagnetics of a LANL-developed prototype waveguide-based optical biosensor — an instrument designed to help in the detection of biological molecules associated with disease using the superior optical properties of single mode planar waveguides.

The CRADA was created to continue work on developing a commercial product that could detect a specific biomarker in urine that could aid in the diagnosis of tuberculosis infection. However, a commercially available product has not yet been built or clinically tested.

“We did develop and validate assays for the detection of tuberculosis specific biological markers, but a clinical trial is necessary to evaluate efficacy of the technology as a diagnostic assay for the disease,” said David Hadley of the Laboratory’s Technology Transfer Division. “LANL did not undertake any instrumentation development of the fieldable model of the biosensor. However, we successfully built and delivered a bench-top version of the instrument under the CRADA and delivered it to Biomagnetics.”

Part of the problem in developing a ready-for-market device is the need for disposable waveguides — which act like fiber-optic cables, channeling light waves through the biosensor. Because non-disposable waveguides are both expensive, and exposed to pathogens like drug-resistant tuberculosis, the need to disinfect them greatly reduces the efficacy of the device. This problem would be solved with the development of inexpensive, disposable waveguides.

The LANL optical biosensor works by exciting fluorescently labeled indicators bound to disease biomarkers using light of appropriate wavelength. Since this excitation happens within the intense optical field of single mode planar waveguides, the sensitivity of the assay is highly enhanced. For the tuberculosis assay, the biomarker being detected specifically on the waveguide-based sensor is something called lipoarabinomannan, a component of the bacterial cell wall.

“LANL delivered the specifications of an assay for one tuberculosis biomarker, lipoarabinomannan, on the bench-top waveguide-based biosensor. This is the biomarker of choice in other urinary tests for the disease as well,” said Hadley.

Through this CRADA, the Laboratory also validated the performance of a cholera toxin assay. However, no clinical testing or testing in contaminated samples was carried out.

“We have made excellent progress under the CRADA towards the detection of tuberculosis-specific biomarkers, instrumentation development, and exploring biomarker choices,“ said Hadley.  “To convert this research and development into a commercial product, the antibodies need to be licensed and the surface chemistry better understood. Then, a field-site in South East Asia or South Africa should be identified where an endemic population, with HIV co-infection, can be evaluated with scientific rigor.”

With further research, scientists at LANL believe that a portable biosensor can become a reality and could greatly improve field-based detection of active tuberculosis infection, a critical need in combating the spread of this infectious disease.